IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO WESTERN DIVISION

UNITED STATES OF AMERICA, **PLAINTIFF,** v. **1961 labeled cases**, more or less, each case containing 36/12 packets of an article of drug in individual cartons, labeled in part: (case) "*** HYDROCORTISONE ACETATE 25MG *** SUPPOSITORIES *** NDC *** Distributed by Ascend Laboratories, LLC Montvale, NJ 07645 ***" *** and other articles of drug, identified above, in various sizes, forms, and various sized containers that are located anywhere on the premises of Masters Pharmaceuticals, Inc., dba RXTPL, 8695 Seward Road, Fairfield, Ohio, to which are affixed labels bearing, among other things, the name and address of the firm for which the manufacturer is identified as Ascend Laboratories, LLC, Montvale, NJ, and Ascend Laboratories, LLC **CLAIMANT/DEFENDANT.**	CASE NO. 1:14-cv-399 CONSENT DECREE FOR CONDEMNATION, DESTRUCTION, AND PERMANENT INJUNCTION

On May 14, 2014, Plaintiff, the United States of America, by and through its undersigned counsel, filed in this Court a

Verified Complaint for Forfeiture In Rem ("Verified Complaint") against the above-captioned articles, which are specifically described in detail in Exhibit A of this Decree ("Articles").

The Verified Complaint alleges that the Articles are drugs within the meaning of 21 U.S.C. § 321(g)(1), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man; and that certain of the Articles (Hydrocortisone Acetate Suppositories 25 mg; Urea Cream 39%; Urea Cream 40%; and Urea Lotion 40%) are also drugs within the meaning of 21 U.S.C. § 321(g)(1)(C) in that they are articles (other than foods) intended to affect the structure or function of the body of man. The Verified Complaint alleges that such Articles may not, under 21 U.S.C. § 355(a), be introduced or delivered for introduction into interstate commerce, because they are new drugs within the meaning of 21 U.S.C. § 321(p) and no approvals of applications filed pursuant to 21 U.S.C. §§ 355(b) or (j) or exemptions from such requirements pursuant to 21 U.S.C. § 355(i) are in effect for such drugs. The Verified Complaint also alleges that such Articles are misbranded while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of 21 U.S.C. § 352(f)(1), in that their labeling fails to bear adequate directions for use, and they are not exempt from such requirement under 21 C.F.R. § 201.115.

Pursuant to a Warrant of Arrest In Rem issued by this Court, the United States Marshal for this District seized the Articles on May 15, 2014 ("May 2014 seizure") at a warehouse located at 8695 Seward Road, Fairfield, Ohio ("Ohio Warehouse"), within the Southern District of Ohio. The Ohio Warehouse is operated by Masters Pharmaceutical, Inc, doing business as RXTPL (hereinafter, "MastersRXTPL"). Thereafter, the United States caused notice of the Verified Complaint and seizure to be published in accordance with the applicable rules of this Court and Rule G of the Supplemental Rules for Admiralty or Maritime and Asset Forfeiture Claims of the Federal Rules of Civil Procedure ("Supplemental Rules"). On June 19, 2014, Ascend Laboratories, LLC ("Claimant/Defendant Ascend"), through its attorney, intervened and filed a claim with respect to the seized Articles in accordance with the Supplemental Rules. Claimant/Defendant Ascend is a New Jersey incorporated firm located at 180 Summit Avenue, Suite 200, Montvale, New Jersey (the "Facility"). Ascend conducts business within the Southern District of Ohio by storing its products, including the Articles, at the Ohio Warehouse and distributing such products, through MastersRXTPL, to its customers within and outside of Ohio. No other party has filed a claim to the Articles.

WHEREAS Claimant/Defendant Ascend having appeared and consented, without contest, to entry of this Decree before any

testimony has been taken, and waiving the filing and service of an amended complaint seeking injunctive relief, and the United States having consented to the entry of this Decree, pursuant to the request of the parties hereto, it is now

ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1345 and 21 U.S.C. §§ 332 and 334, and personal jurisdiction over all parties to this action. Venue is proper in this district under 28 U.S.C. §§ 1391(b) and 1395.

2. Claimant/Defendant Ascend affirms that it is the sole owner of the seized Articles and that no other person has an interest in such Articles. Claimant/Defendant Ascend further affirms that it will hold the United States harmless should any party or parties hereafter file or seek to file a claim to intervene in this action, or seek to defend or to obtain any part of the Articles subject to this Decree.

3. The Articles are drugs within the meaning of 21 U.S.C. § 321(g)(1)(B), in that they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man. Certain of the Articles (Hydrocortisone Acetate Suppositories 25 mg; Urea Cream 39%; Urea Cream 40%; and Urea Lotion 40%) are also drugs within the meaning of 21 U.S.C. § 321(g)(1)(C) in that they are articles (other than foods)

intended to affect the structure or function of the body of man. The Articles may not be introduced or delivered for introduction into interstate commerce under 21 U.S.C. § 355(a) because they are "new drugs" within the meaning of 21 U.S.C. § 321(p), and no approvals of applications filed under 21 U.S.C. §§ 355(b) or (j) or exemptions from such requirements under 21 U.S.C. § 355(i) are in effect for such drugs.

4. The Articles are misbranded within the meaning of the Act, 21 U.S.C. § 352(f)(1), while held for sale after shipment of one or more of their components in interstate commerce, 21 U.S.C. § 334, in that their labeling fails to bear adequate directions for use and they are not exempt from such requirement under 21 C.F.R. § 201.115 because the Articles are unapproved new drugs.

5. The seized Articles, therefore, are condemned pursuant to 21 U.S.C. § 334(a) and forfeited to the United States.

6. Claimant/Defendant Ascend shall pay to the United States all court costs and fees, storage, and other proper expenses, including the cost of destroying the condemned Articles, and such further costs for which it is liable pursuant to 21 U.S.C. § 334(e). Claimant/Defendant Ascend shall pay these costs within ten (10) business days after receiving notice of such costs from the United States Food and Drug Administration ("FDA"), the United States Marshals Service (the

"USMS"), and/or the United States Department of Justice ("DOJ").

7. Within fifteen (15) business days after the entry of this Decree, Claimant/Defendant Ascend shall execute and file with the Clerk of this Court a good and sufficient penal bond ("Bond") with surety in the amount of six million and five hundred thousand dollars ($6,500,000) to be applied to Lot 1 of the condemned Articles (as described in paragraph 10(A) and held for application to the succeeding Lot 2 (as described in paragraph 10(B)). The Bond shall be in a form acceptable to the Clerk of this Court and payable to the United States of America, and conditioned on Claimant/Defendant Ascend abiding by and performing all of the terms and conditions of this Decree and of such further orders and decrees as may be entered in this proceeding.

8. Within twenty (20) business days after filing the Bond pursuant to paragraph 7, Claimant/Defendant Ascend shall give written notice to FDA that, at its own expense and under FDA's supervision, it is prepared to destroy: (i) the condemned Articles and (ii) any Pramoxine-HT Otic Drops, Hydrocortisone Acetate Suppositories 25 mg, Urea Cream 39%, Urea Cream 40%, and Urea Lotion 40% manufactured for Claimant/Defendant Ascend and returned by customers to Claimant/Defendant Ascend, through MastersRXTPL, following the May 2014 seizure (hereafter, "the Returned Products"). Claimant/Defendant Ascend's notice shall

specify the proposed time, place, and method of destruction of the condemned Articles and Returned Products (the "Destruction Plan").

9. Claimant/Defendant Ascend shall not commence or permit any other person to commence destroying the condemned Articles or the Returned Products until it has received written authorization from FDA to commence the destruction.

10. Following Claimant/Defendant Ascend's payment of costs and posting of the Bond, as required by paragraphs 6 and 7 of this Decree, the USMS, upon notice from FDA that Claimant/Defendant Ascend is authorized to commence destroying the condemned Articles, shall release the appropriate Lot of the condemned Articles (as described in subparagraphs (A)-(B) of this paragraph) to Claimant/Defendant Ascend's custody for the sole purpose of destroying the condemned Articles under FDA supervision and in compliance with the Destruction Plan described in paragraph 8. The schedule for release of the condemned Articles is as follows:

A. The condemned Articles in Lot 1, consisting of approximately 1/2 of the condemned Articles (by value), to be further designed by FDA, stored at the Ohio Warehouse, shall be released to Claimant/Defendant Ascend for the sole purpose of destroying Lot 1.

B. If and only if Lot 1 has been released and

Claimant/Defendant Ascend destroys Lot 1 under FDA supervision and in accordance with the Destruction Plan described in paragraph 8, the condemned Lot 2, consisting of approximately a second 1/2 of the condemned Articles (by value), to be further designed by FDA, at the Ohio Warehouse, shall be released to Claimant/Defendant Ascend for the sole purpose of destroying Lot 2.

11. Within fifteen (15) business days after receiving written authorization from FDA to commence destroying the condemned Articles, Claimant/Defendant Ascend shall, under FDA supervision, complete the destruction of all Lots of the condemned Articles and Returned Products in compliance with this Decree. Defendants shall reimburse the United States, at the rates set forth in paragraph 23 of this Decree, for the supervision of the destruction within ten (10) business days after receiving notice of such costs from FDA.

12. Claimant/Defendant Ascend shall at all times, until all of the condemned Articles and Returned Products have been destroyed in accordance with this Decree, retain the condemned Articles and Returned Products in its custody intact for examination or inspection by FDA in a place made known to and approved by FDA, and shall maintain all records or other proof necessary to establish the identity of the condemned Articles to FDA's satisfaction.

13. Claimant/Defendant Ascend shall not cause the condemned Articles or Returned Products to be disposed of in a manner contrary to the Act, or other laws of the United States, or of any State or Territory (as defined in the Act) in which they are disposed.

14. If Claimant/Defendant Ascend breaches any condition of this Decree, or any subsequent decree or order in this proceeding, it shall, at its own expense, immediately return to the USMS any and all remaining condemned Articles in its custody that have been released for destruction pursuant to paragraph 10. Following return of the condemned Articles, the USMS shall destroy the condemned Articles and make due return to this Court regarding their disposition. In the event that return of any of the condemned Articles becomes necessary under this paragraph, Claimant/Defendant Ascend shall be responsible for all costs of storage and disposition incurred by the United States.

15. If Claimant/Defendant Ascend does not avail itself of the opportunity to repossess and destroy the condemned Articles in the manner provided in this Decree, or if any portion of the condemned Articles remain in the USMS's custody after expiration of the twenty (20) day time period described in paragraph 8, the USMS will destroy such condemned Articles and make due return to this Court regarding their disposition. Claimant/Defendant Ascend shall bear the costs of storage and destruction that are

incurred by the United States pursuant to this paragraph, and shall pay such costs within ten (10) business days after receiving an invoice from FDA, the USMS, or DOJ.

16. If Claimant/Defendant Ascend fails to abide by and perform all the terms and conditions of this Decree, or of the Bond, or any such further order or decree as may be entered in this proceeding relating to the condemned Articles, then, on motion of the United States in this proceeding, the Bond shall be forfeited in its entirety to the United States and judgment entered thereon in favor of Plaintiff, and any condemned articles remaining in the custody of the USMS shall be forfeited and disposed of pursuant to further order of this Court.

17. DOJ, upon being advised by FDA that all of the condemned Articles and Returned Products have been destroyed in compliance with this Decree and that Claimant/Defendant Ascend has paid all costs as of that date in accordance with paragraphs 6 and 11, will transmit such information to the Clerk of this Court, whereupon the Bond given in this proceeding shall be discharged.

18. Upon entry of this Decree, Claimant/Defendant Ascend and each and all of its agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (the "Associated Person(s)") who receive notice of this Decree are

hereby permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any act that:

A. Violates the Act, 21 U.S.C. § 331(d), and results in the introduction or delivery for introduction into interstate commerce of new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(b) or (j), nor exempt from approval pursuant to 21 U.S.C. § 355(i); or

B. Violates the Act, 21 U.S.C. § 331(a), and results in the introduction or delivery for introduction into interstate commerce of drugs that are misbranded in that their labeling fails to bear adequate directions for use; or

C. Violates the Act, 21 U.S.C. § 331(k), and results in an article of drug becoming misbranded, in that its labeling fails to bear adequate directions for use, while held for sale after shipment of one or more of its components in interstate commerce.

19. Upon entry of this Decree, Claimant/Defendant Ascend and each and all of its Associated Person(s) who receive notice of this Decree are permanently restrained and enjoined under 21 U.S.C. § 332(a) from:

A. Introducing or delivering for introduction into interstate commerce, manufacturing, processing, packaging, labeling, holding, or selling Hydrocortisone Acetate

Suppositories 25 mg, Pramoxine-HC Otic Drops, Urea Cream 39%, Urea Cream 40%, and Urea Lotion 40%; or any product labeled similarly to such products and containing the same active ingredients; or any other product that is a new drug within the meaning of 21 U.S.C. § 321(p), unless and until an approved new drug application or an abbreviated new drug application or an investigational new drug application filed pursuant to 21 U.S.C. §§ 355(b), (j), or (i), held by Claimant/Defendant Ascend, is in effect for such drugs;

B. Introducing or delivering for introduction into interstate commerce, manufacturing, processing, packing, labeling, holding, or selling drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) in that their labeling fails to bear adequate directions for use, including but not limited to Hydrocortisone Acetate Suppositories 25 mg, Pramoxine-HC Otic Drops, Urea Cream 39%, Urea Cream 40%, and Urea Lotion 40%; or causing the misbranding of any drug, in that their labeling fails to bear adequate directions for use, while such drug is held for sale after shipment of one or more its components in interstate commerce.

20. Upon entry of this Decree, if at any time FDA determines, based on the results of an inspection, the analysis of a sample, a report, or any other information, that Claimant/Defendant Ascend has failed to comply with any

provision of this Decree, has violated the Act or its implementing regulations, and/or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Claimant/Defendant Ascend in writing of the noncompliance and order Claimant/Defendant Ascend to take appropriate corrective action, including, but not limited to, ordering Claimant/Defendant Ascend to immediately take one or more of the following actions:

A. Cease manufacturing, processing, preparing, packing, labeling, holding, selling, and/or distributing any or all drugs that are unapproved or that are misbranded in that their labeling fails to bear adequate directions for use;

B. Recall, at Claimant/Defendant Ascend's expense, any drug products that are unapproved; or misbranded in that their labeling fails to bear adequate directions for use; or otherwise in violation of this Decree, the Act, or its implementing regulations;

C. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

D. Submit additional reports or information to FDA as requested;

E. Pay liquidated damages as described in paragraph 30; and/or

F. Take any other corrective actions as FDA, in its discretion, deems necessary to bring Claimant/Defendant Ascend into compliance with this Decree, the Act, and its implementing regulations.

The provisions of this paragraph shall be apart from, and in addition to, all other remedies available to FDA.

21. Upon receipt of any order issued by FDA pursuant to paragraph 20, Claimant/Defendant Ascend shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in paragraph 20 shall continue until Claimant/Defendant Ascend receives written notification from FDA that Claimant/Defendant Ascend appears to be in compliance with this Decree, the Act, and its implementing regulations, and that Claimant/Defendant Ascend may, therefore, resume operations.

22. FDA shall be permitted, without prior notice and when FDA deems necessary, to make inspections of the Facility, and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and FDA regulations. During inspections of the Facility, FDA shall be permitted to have immediate access to buildings, equipment, raw ingredients, in-process materials, finished products, containers, packing material, labeling, and other material therein; take photographs and make video

recordings; take samples of raw ingredients, in-process materials, finished products, containers, packing material, labeling, and other material; and examine and copy all records relating to the manufacture, preparing, packing, labeling, holding, and distribution of any and all drugs and their respective components. The inspection authority granted by this Decree is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

23. Claimant/Defendant Ascend shall reimburse the United States for the costs of supervising Claimant/Defendant Ascend's destruction of the condemned Articles, and for costs associated with all inspections, examinations, reviews, evaluations, and analyses conducted pursuant to this Decree, at the standard rates prevailing at the time the activities are accomplished. As of the date this Decree is signed by the parties, the rates are $88.45 per hour or fraction thereof per representative for supervision other than laboratory and analytical work; $106.03 per hour or fraction thereof per representative for laboratory and analytical work; and $.56 per mile for travel expenses for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses, where necessary. In the event that the

standard rates generally applicable to FDA's supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of this Court.

24. Within ten (10) business days after entry of this Decree, Claimant/Defendant Ascend shall post a copy of this Decree in a common area at the Facility and shall ensure that the Decree remains posted for as long as it remains in effect. In the event that Claimant/Defendant Ascend relocates its facility, Claimant/Defendant Ascend shall ensure that a copy of the Decree is posted at in a common area at the new facility. Within twenty (20) business days after entry of this Decree, Claimant/Defendant Ascend shall provide an affidavit stating the fact and manner of its compliance with this paragraph.

25. Within ten (10) business days after entry of this Decree, Claimant/Defendant Ascend shall provide a copy of the Decree by personal service or certified mail (restricted delivery, return receipt requested) to each of the Associated Person(s). Within ten (10) business days after entry of this Decree, Claimant/Defendant Ascend shall provide a copy of the Decree by personal service or certified mail (restricted delivery, return receipt requested) to Sonar Products, Inc.; Acino Products, LLC; MastersRXTPL; Crown Laboratories, Inc.; and any other entity with which Claimant/Defendant Ascend has contracted to manufacture or distribute the Articles into

interstate commerce. Within twenty (20) business days after entry of this Decree, Claimant/Defendant Ascend shall provide to FDA an affidavit stating the fact and manner of its compliance with this paragraph, and identifying the names, addresses, and positions of all persons who have received a copy of this Decree.

26. In the event that Claimant/Defendant Ascend becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Claimant/Defendant Ascend shall immediately provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Each time Claimant/Defendant Ascend becomes associated with an additional Associated Person(s), it shall, within ten (10) business days, provide to FDA an affidavit stating the fact and manner of its compliance with this paragraph, identifying the names, addresses, and positions of all Associated Person(s) who received a copy of this Decree pursuant to this paragraph. Within ten (10) business days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate compliance with this paragraph, Claimant/Defendant Ascend shall provide such information or documentation to FDA.

27. Claimant/Defendant Ascend shall notify FDA in writing at least ten (10) business days before any change in ownership,

name, or character of its business that occurs after entry of this Decree, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of Ascend Laboratories, LLC, or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Claimant/Defendant Ascend shall provide a copy of this Decree to any prospective successor or assign at least twenty (20) business days prior to any sale or assignment. Claimant/Defendant Ascend shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) business days prior to such assignment or change in ownership.

28. Claimant/Defendant Ascend shall abide by the decisions of FDA and its representatives, which shall be final. All decisions specified in this Decree shall be vested in FDA's discretion and, if necessary, shall be reviewed by this Court pursuant to the arbitrary and capricious standard as set forth in 5 U.S.C. § 706(2)(A). Review by a court of any FDA decision rendered pursuant to this Decree shall be based exclusively upon the written record before FDA at the time of the decision. No discovery shall be taken by either party.

29. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall reference the

civil action number (1:14-cv-399), be prominently marked "Ascend Laboratories, LLC," and be addressed to:

District Director
New Jersey District Office
U.S. Food and Drug Administration
10 Waterview Blvd.
Parsippany, New Jersey 07054

30. Should Claimant/Defendant Ascend fail to comply with any provision of this Decree, the Act, or its implementing regulations, it shall pay to the United States of America the sum of twenty thousand dollars ($20,000) in liquidated damages for each day such violation continues and an additional sum of seven thousand five hundred dollars ($7,500) in liquidated damages for each violation of this Decree, the Act, or its implementing regulations, and an additional sum equal to five (5) times the retail value of each shipment of an unapproved new drug and/or a drug that is misbranded in that its labeling fails to bear adequate directions for use in liquidated damages for each such unlawful shipment. Claimant/Defendant Ascend understands and agrees that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, and the Court to impose, additional criminal or civil penalties based on conduct that may also be the basis for payment of the liquidated damages.

31. Should the United States bring, and prevail in, a

contempt action to enforce the terms of this Decree, Claimant/Defendant Ascend shall, in addition to other remedies, reimburse the United States for its attorneys' fees and overhead, investigational and analytical expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, administrative court costs, and any other costs or fees relating to such proceedings.

32. If Claimant/Defendant Ascend has maintained to FDA's satisfaction a state of continuous compliance with the Act, applicable regulations, and this Decree for at least sixty (60) months after satisfying all of their obligations under this Decree, Claimant/Defendant Ascend may petition this court for relief from this Decree, and the United States will not oppose such petition.

33. This Court retains jurisdiction over this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED.

Dated this 28th day of September 2014.

UNITED STATES DISTRICT JUDGE

Exhibit A

DEFENDANT 1:

1961 labeled cases, more or less, each case containing 36/12 packets of an article of drug in individual cartons, labeled in part:

(case)
"*** HYDROCORTISONE ACETATE 25MG 12's SUPPOSITORIES *** NDC 67877 - 312- 12 *** Distributed by Ascend Laboratories, LLC, Montvale, NJ 07645 ***"

(carton)
"*** ASCEND *** Laboratories, LLC *** NDC 67877-312-12 *** Hydrocortisone Acetate Suppositories *** 25 mg *** For Rectal Administration *** Rx Only *** 12 Adult Suppositories *** Manufactured for: *** Ascend Laboratories, LLC *** Montvale, NJ 07645 ***"; and

595 labeled cases, more or less, each case containing 36/24 packets of an article of drug in individual cartons, labeled in part:

(case)
"*** HYDROCORTISONE ACETATE 25MG 24's Suppositories *** NDC 67877 - 312 - 24 *** Distributed By Ascend Laboratories, LLC Montvale, NJ 07645 ***"

(carton)
"*** ASCEND *** Laboratories, LLC *** NDC 67877-312-24 *** Hydrocortisone Acetate Suppositories *** 25 mg *** For Rectal Administration *** Rx Only *** 24 Adult Suppositories *** Manufactured for: *** Ascend Laboratories, LLC *** Montvale, NJ 07645 ***";

and

DEFENDANT 2:

124 labeled cases, more or less, each case containing 144/10 mL bottles of an article of drug labeled in part:

(case)
"*** 67877-269-11 *** 10 mL *** Pramoxine - HC Otic Drops ***Ascend Laboratories, LLC ***"

(bottle)

"*** ASCEND *** Laboratories, LLC *** NDC 67877-269-11 *** Rx Only *** Pramoxine-HC Otic Drops *** 10 mL *** Manufactured for: *** Ascend Laboratories, LLC *** Montvale, NJ 07645 ***";

and

DEFENDANT 3:

96 labeled cases, more or less, each case containing 12/8 ounce bottles of an article of drug in individual cartons, labeled in part:

(case)
"*** NDC # 67877-305-12 *** ASCEND *** Urea Cream 39% *** Manufactured for: Ascend Laboratories, LLC Montvale, NJ 07645"

(carton)
"*** ASCEND *** Laboratories, LLC *** NDC 67877-305-12 *** Urea Cream *** 39% *** For Topical Use Only *** Rx Only *** NET WT *** 8 OZ *** (227g)*** Manufactured for: *** Ascend Laboratories, LLC *** Montvale, NJ 07645 ***"; and

1794 labeled cases, more or less, each case containing 72/1 ounce tubes of an article of drug in individual cartons, labeled in part:

(case)
"*** NDC # 67877-272-21 *** ASCEND *** Urea Cream 40% *** Manufactured for: Ascend Laboratories, LLC Montvale, NJ 07645 ***"

(carton)
"*** ASCEND *** Laboratories, LLC *** NDC 67877-272-21 *** Urea Cream *** 40% *** For Topical Use Only *** Rx Only *** NET WT *** 1 OZ *** (28.35g) *** Manufactured for: *** Ascend Laboratories, LLC *** Montvale, NJ 07645 ***"; and

1989 labeled cases, more or less, each case containing 12/3 ounce tubes of an article of drug in individual cartons, labeled in part:

(case)
"*** NDC # 67877-272-03 *** ASCEND *** Urea Cream 40% *** Manufactured for: Ascend Laboratories, LLC Montvale, NJ 07645"

(carton)
"*** ASCEND *** Laboratories, LLC *** NDC 67877-272-03 *** Urea Cream *** 40% *** For Topical Use Only *** Rx Only *** NET WT *** 3 OZ *** (85.05g)*** Manufactured for: *** Ascend Laboratories, LLC *** Montvale, NJ 07645 ***"; and

1340 labeled cases, more or less, each case containing 12/7 ounce tubes of an article of drug in individual cartons, labeled in part:

(case)
"*** NDC # 67877-272-07 *** ASCEND *** Urea Cream 40% *** Manufactured for: Ascend Laboratories, LLC Montvale, NJ 07645***"

(carton)
"*** ASCEND *** Laboratories, LLC *** NDC 67877-272-07 *** Urea Cream *** 40% *** For Topical Use Only *** Rx Only *** NET WT *** 7 OZ *** (198.6g) *** Manufactured for: *** Ascend Laboratories, LLC *** Montvale, NJ 07645 ***"; and

983 labeled cases, more or less, each case containing 12/8 ounce bottles of an article of drug in individual cartons, labeled in part:

(case)
"*** NDC # 67877-273-12 *** ASCEND *** Urea Lotion 40% *** Manufactured for: Ascend Laboratories, LLC Montvale, NJ 07645"

(carton)
"*** ASCEND *** Laboratories, LLC *** NDC 67877-273-12 *** Urea Lotion *** 40% *** For Topical Use Only *** Rx Only *** 8 fl oz *** (236.6g) *** Manufactured for: *** Ascend Laboratories, LLC *** Montvale, NJ 07645 ***";

and

DEFENDANT 4:
other articles of drug, identified above, in various sizes, forms, and various sized containers that are located anywhere on the premises of Masters Pharmaceuticals, Inc., dba RXTPL, 8695 Seward Road, Fairfield, Ohio, to which are affixed labels bearing, among other things, the name and address of the firm for which the manufacturer is identified as Ascend Laboratories, LLC, Montvale, NJ.

We hereby consent to the entry of the foregoing Consent Decree:

Claimant and Defendants

S. Venkatesh, CEO of Ascend Laboratories, LLC, Individually and on behalf of Ascend Laboratories, LLC

Steven C. Coffaro
Attorney for S. Venkatesh and Ascend Laboratories, LLC

Plaintiff

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